EXHIBIT D

FW: Covid 19 study

From: "Murray, Jeffrey S" <jeffrey.murray@fda.hhs.gov>
To: "Winestock, Karen" <karen.winestock@fda.hhs.gov>; "Akunne, Linda" <linda.akunne@fda.hhs.gov>; "Sheikh, Virginia" <virginia.sheikh@fda.hhs.gov>
Date: Thu, 12 Mar 2020 18:10:05 +0000

AACCCK!!

From: Jay Lalezari <drjay@questclinical.com>
Sent: Thursday, March 12, 2020 2:03 PM
To: Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov>
Cc: Struble, Kimberly <Kimberly.Struble@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Nader Pourhassan <npourhassan@cytodyn.com>; Kush Dhody <kushd@amarexcro.com>; Bruce Patterson <brucep@incelldx.com>
Subject: Covid 19 study

Dear Jeff,

I have become the interim CMO for Cytodyn to help facilitate discussions around the proposed Covid 19 protocol.

We are sending you a revised protocol tomorrow for a 75 pt study with a 2:1 randomization to drug:placebo.

If we are able to show proof of efficacy, we would hope to quickly move to a combination study with an antiviral.

Kind regards,
Jay Lalezari, MD
415-353-0800

> On Mar 11, 2020, at 10:15 AM, Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov> wrote:
>
> Jay,
>
> I agree that antivirals or antivirals alone may not be the answer to serious respiratory diseases. There are sponsors and investigators proposing host directed therapies, that have some underlying scientific rationale. We are willing to work with sponsors to have randomized trials comparing investigational agents (with nonclinical rationale) to placebo that will provide us with answers.
>
> Since you are not the sponsor of this particular IND, I can't talk to you about go/no go decisions. You will need to talk to the sponsor about any actions.
>
> Jeff
>
> > **From:** Jay Lalezari <drjay@questclinical.com>
> > **Sent:** Wednesday, March 11, 2020 1:07 PM
> > **To:** Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov>
> > **Cc:** Struble, Kimberly <Kimberly.Struble@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>
> > **Subject:** Re: covid 19
> >
> > Hi Jeff, Kimberly, and Debra.
> >
> > We did the phase II/III zanamavir studies. Antivirals reduce viral shedding of flu from nasal swabs from about 5 days in untreated infection down to about 2. But those studies were of marginal clinical benefit even when started early (they are much better at prophylaxis). It isn't the virus that drives clinical illness and death, its the immune system.
> >
> > The surprising preliminary results in our patients with breast cancer (tumors shrinking and CTCs going negative) are starting to make an argument to support the effects of Leronlimab on cell trafficking that have been proposed. Would love to see a clean monotherapy study of Leronlimab in women and other patients with cancer who are in remission but have persistent CTCs to understand the effects and importance of this activity, but that is a different convo.
> >
> > I think the anti tumor effects apparently mediated by cell trafficking along with the clear safety profile

provide a rationale for wanting to look at Leronlimab on Covid 19 infection to mitigate inflammation and the over reaction of the immune system causing high mortality rates. Obviously, the ideal regimen would include an antiviral and immune modulator together. If you could set that up, we'd be happy to jump in.

In the meantime, I just need a go/no go to set up a space to see Covid patients that won't put our HIV and cancer pts at risk.

To the extent its possible, I remain an independant party in all of the this (no financial stake other than running the research program).

I was interviewed for a short article in a local paper. It is embargoed until you make a decision. A draft is attached below.

Happy to chat further if I can be of any assistance.
Oy.
Best,
Jay

415-353-0800

> On Mar 11, 2020, at 9:39 AM, Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov> wrote:
>
> Jay,
>
> As an investigator, why would you choose to use this drug rather than be involved with either the NIH or Gilead remdesivir trials? Remedesivir has decent in vitro activity against SARS CoV-2, one of few drugs tested so far. What compelling nonclinical data support the use of leronlimab for COVID-19 over other drugs that have been prioritized? In addition, we are not enthused about single arm trials or compassionate use for products that don't have good evidence of activity nor for drugs that might have unfavorable toxicity profiles (latter is not the case for leronlimab). What is gained if we never learn if drugs are active or harmful? Can we afford to waste time or resources on products with low potential?
>
> Jeff
>
> -----Original Message-----
> From: Jay Lalezari <drjay@questclinical.com>
> Sent: Wednesday, March 11, 2020 12:29 PM
> To: Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov>
> Cc: Jay Lalezari <drjay@questclinical.com>
> Subject: covid 19
>
> Hi Jeff,
>
> Quest Research in SF is trying to rapidly gear up for a Covid 19 treatment study with Leronlimab/Cytodyn. I believe your group is reviewing the protocol. Am I allowed to speak with you about it?
>
> We need to make some urgent logistical decisions. For example, if we are doing a treatment study we need to secure space that is safely removed from our HIV and cancer patients.
>
> Let me know if we can chat or if you can give me a sense of timelines.
> Thx,
>
> Jay Lalezari, MD
> Director, Quest Research
> 415-353-0800